| From the INTERNATIONAL SEARCHING AUTHORITY   |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
| То:  | DOMESTICS .  |  |  |  |  |  |
| DIANNE E. REED   | PCT  |  |  |  |  |  |
| REED & ASSOCIATES  | NOTIFICATION OF TRANSMITTAL OF   |  |  |  |  |  |
| 800 MENLO AVENUE   |  |  |  |  |  |  |
| SUITE 210  | THE INTERNATIONAL SEARCH REPORT  |  |  |  |  |  |
| MENLO PARK, CA 94025   | OR THE DECLARATION   |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | (PCT Rule 44.1)  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Date of Mailing  |  |  |  |  |  |
|  | (day/month/year) 18 MAR 2002   |  |  |  |  |  |
| Applicant's or agent's file reference  | LO MATERIOUS   |  |  |  |  |  |
| 0300-0014.40   | FOR FURTHER ACTION See paragraphs 1 and 4 below  |  |  |  |  |  |
|  | TORTORTHER ACTION See paragraphs 1 and 4 below   |  |  |  |  |  |
| International application No.  | International filing date  |  |  |  |  |  |
| PCT/US01/23046   | (day/month/year)   |  |  |  |  |  |
|  | 20 July 2001 (20.07.2991)  |  |  |  |  |  |
| Applicant  |  |  |  |  |  |  |
| GLAXO GROUP LIMITED  | MAW 3/21/02 /10  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | The state of the s |  |  |  |  |  |
| 1. The applicant is hereby notified that the international search n  | 6150 10 3 1 d 1 m  |  |  |  |  |  |
| Filing of amendments and statement under Article 19:   | Case absolute  |  |  |  |  |  |
| The applicant is entitled, if he so wishes, to amend the claims  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| When? The time limit for filing such amendments is norm  |  |  |  |  |  |  |
| international search report; however, for more det   | 1  |  |  |  |  |  |
| Where? Directly to the International Bureau of WIPO  | Deep 105 4/18  |  |  |  |  |  |
| 34, chemin des Colombettes   | 0300 - 00. 11-0  |  |  |  |  |  |
| 1211 Geneva 20, Switzerland  | 100 H/cc   |  |  |  |  |  |
| Facsimile No.: (41-22) 740.14.35   | Auff 123 1/18  |  |  |  |  |  |
| For more detailed instructions, see the notes on the accompanying sheet.   |  |  |  |  |  |  |
| The state of the s |  |  |  |  |  |  |
| 2. The applicant is hereby notified that no international search report will be established and that the declaration under   |  |  |  |  |  |  |
| Article 17(2)(a) to that effect is transmitted herewith.   |  |  |  |  |  |  |
| ·  |  |  |  |  |  |  |
| 3. With regard to the protest against payment of (an) additions  | al fee(s) under Rule 40.2, the applicant is notified that:   |  |  |  |  |  |
|  |  |  |  |  |  |  |
| ·  | transmitted to the International Bureau together with the  |  |  |  |  |  |
| applicant's request to forward the texts of both the prot  | test and the decision thereon to the designated Offices.   |  |  |  |  |  |
| no decision has been made yet on the protest; the applic   | eant will be notified as soon as a decision is made.   |  |  |  |  |  |
|  | #  |  |  |  |  |  |
| 4. Further action(s): The applicant is reminded of the following:  | See  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Shortly after 18 months from the priority date, the international application will be published by the International Bureau.   |  |  |  |  |  |  |
| Shortly after 18 months from the priority date, the international application will be published by the International Bureau.  If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3. respectively, before the completion of the technical preparations for international publication.  |  |  |  |  |  |  |
| completion of the technical preparations for international publicati   | on.  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Within 19 months from the priority date, a demand for international p  |  |  |  |  |  |  |
| wishes to postpone the entry into the national phase until 30 month  | ns from the priority date (in some Offices even later).  |  |  |  |  |  |
| Within 20 months from the priority date, the applicant must perform  | the prescribed acts for entry into the national phase  |  |  |  |  |  |
| before all designated Offices which have not been elected in the d   | emand or in a later election within 19 months, from the  |  |  |  |  |  |
| priority date or could not be elected because they are not bound by  | y Chapter II.  |  |  |  |  |  |
| ·  |  |  |  |  |  |  |
| Name and mailing address of the YCA/YIC  | Authorized officer   |  |  |  |  |  |
| Name and mailing address of the ISA/US   | T 41 - 7 - (Assessed 9)  |  |  |  |  |  |
| Commissioner of Patents and Trademarks   | Bradley L. Sisson  |  |  |  |  |  |
| Box PCT  | ( Diagley E. Sieson  |  |  |  |  |  |
| Washington, D.C. 20231   | Telephone No. (703) 308-0196   |  |  |  |  |  |
| Facsimile No. (703)305-3230  | 1 totophone 110. (100) 000 0170  |  |  |  |  |  |
| Form PCT/ISA/220 (July 1998)   |  |  |  |  |  |  |



# From the INTERNATIONAL SEARCHING AUTHORITY To: DIANNE E. REED **REED & ASSOCIATES** NOTIFICATION OF TRANSMITTAL OF 800 MENLO AVENUE THE INTERNATIONAL SEARCH REPORT SUITE 210 OR THE DECLARATION MENLO PARK, CA 94025 (PCT Rule 44.1) Date of Mailing 18 MAR 2002 (day/month/year) Applicant's or agent's file reference 0300-0014.40 FOR FURTHER ACTION See paragraphs 1 and 4 below International application No. International filing date PCT/US01/23046 (day/month/year) 20 July 2001 (20.07.2001) Applicant **GLAXO GROUP LIMITED** The applicant is hereby notified that the international search report has been established and is transmitted herewith. Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46): When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompany sheet. Where? Directly to the International Bureau of WIPO 34. chemin des Colombettes 1211 Geneva 20 Switzerland Facsimile No.: (41-22) 740.14.35 For more detailed instructions, see the notes on the accompanying sheet. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that: the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices. no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made. Further action(s): The applicant is reminded of the following: Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication. Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later). Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II. Authorized officer Lawrence For Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230 Telephone No. (703) 308-0196



# **PCT**

# INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applic<br>0300-0   |   | or agent's file reference<br>0   | FOR FURTHER<br>ACTION  | see Notific<br>(Form PC<br>below. | cation of Transmitta<br>T/ISA/220) as well | al of International Search Report as, where applicable, item 5 |  |  |         |   |  |                                 |  |  |   |
|--|---|--|--|-----------------------------------|--|--|--|--|---------|---|--|---------------------------------|--|--|---|
| International application No. PCT/US01/23046   |   |  | International filing date (day/month/year) 20 July 2001 (20.07.2001) |                                   | (Earliest) Prior<br>20 July 2000 (         | rity Date (day/month/year)<br>20.07.2000)                      |  |  |         |   |  |                                 |  |  |   |
| Applicant GLAXO GROUP LIMITED  |   |  |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   |  |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
| This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.   |   |  |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
| This in  | nternat   | tional search report consists  | of a total of 4 sheets.  |                                   |  | •  |  |  |         |   |  |                                 |  |  |   |
| It is also accompanied by a copy of each prior art document cited in this report.  |   |  |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
| 1. Basis of the Report  a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)). |   |  |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   |  |  |                                   |  |  |  |  | b.<br>г |   | Vith regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international earch was carried out on the basis of the sequence listing: |                                 |  |  |   |
|  |   |  |  |                                   |  |  |  |  | Ļ       | _ |  | al application in written form, |  |  | • |
|  | _   | filed together with the international application in computer readable form.   |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   | furnished subsequently to this Authority in written form.  |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
| 2  | 걸   | furnished subsequently to the  | nis Authority in computer readable                                   | form.                             |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   | the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.   |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   | the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.   |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
| 2.   |   | Certain claims were found  | l unsearchable (See Box I).  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
| 3. 2<br>4. V   | X<br>Vith re  | Unity of invention is lacking gard to the title,   | ng (See Box II).   |                                   |  | et de  |  |  |         |   |  |                                 |  |  |   |
|  | $\boxtimes$   | the text is approved as subn   | nitted by the applicant.   |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   | the text has been established  | d by this Authority to read as follow                                | ws:                               |  |  |  |  |         |   |  |                                 |  |  |   |
| _  |   |  |  |                                   |  | •  |  |  |         |   |  |                                 |  |  |   |
| 5. V   | Vith re   | egard to the abstract,   |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  | $\boxtimes$   | the text is approved as subn   | nitted by the applicant.   |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   | the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority. |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
| 6. <u>T</u>  | 6. The figure of the drawings to be published with the abstract is Figure No. |  |  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   | as suggested by the applicar   | at.  |                                   | $\boxtimes$                                | None of the figures  |  |  |         |   |  |                                 |  |  |   |
|  | _]  | because the applicant failed   | to suggest a figure.   |                                   |  |  |  |  |         |   |  |                                 |  |  |   |
|  |   | because this figure better ch  | naracterizes the invention.  |                                   |  |  |  |  |         |   |  |                                 |  |  |   |

Form PCT/ISA/210 (first sheet) (July 1998)



International application No.

PCT/US01/23046

| Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)                                       |  |  |  |  |  |
|---|--|--|--|--|--|
| This interna  | tional report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:  |  |  |  |  |
| 1.  | Claim Nos.: because they relate to subject matter not required to be searched by this Authority, namely:   |  |  |  |  |
| 2.  | Claim Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  |  |  |  |  |
| 3. 6.4(a).  | Claim Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule  |  |  |  |  |
| Box II Ol   | servations where unity of invention is lacking (Continuation of Item 2 of first sheet)   |  |  |  |  |
| This International Searching Authority found multiple inventions in this international application, as follows: Please See Continuation Sheet |  |  |  |  |  |
|   |  |  |  |  |  |
|   |  |  |  |  |  |
|   |  |  |  |  |  |
| 1.  | As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.   |  |  |  |  |
| 2.  | As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.   |  |  |  |  |
| 3.  | As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:   |  |  |  |  |
|   |  |  |  |  |  |
|   |  |  |  |  |  |
| 4.  | No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-5 and 32-40 to the extent that they read on SEQ ID NO:8 |  |  |  |  |
| Remark on   | Protest  |  |  |  |  |
|   |  |  |  |  |  |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/23046

| A. CLASSIFICATION OF SUBJECT MATTER  IPC(7) : C07K 7/00  US CL : 530/328   |  |   |                                  |  |  |  |  |
|--|--|---|----------------------------------|--|--|--|--|
| According to International Patent Classification (IPC) or to both national classification and IPC  B. FIELDS SEARCHED                                      |  |   |                                  |  |  |  |  |
| Minimum documentation searched (classification system followed by classification symbols) U.S.: 530/328, 350   |  |   |                                  |  |  |  |  |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched                              |  |   |                                  |  |  |  |  |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet |  |   |                                  |  |  |  |  |
| C. DOC   | UMENTS CONSIDERED TO BE RELEVANT   |   |                                  |  |  |  |  |
| Category *   | Citation of document, with indication, where ap  | opropriate, of the relevant passages  | Relevant to claim No.            |  |  |  |  |
| Α  | EP 0 494 260 B1 (SMITH et al.) 14 June 1995 (14.   | 06.1995), see entire document.  | 1-5 and 32-40                    |  |  |  |  |
| A  | US 5,589,456 A (SMITH et al.) 31 December 1996   | (31.12.1996), se entire document.   | 1-5, 32-40                       |  |  |  |  |
|  |  |   |                                  |  |  |  |  |
|  |  |   |                                  |  |  |  |  |
| ."   |  |   |                                  |  |  |  |  |
|  |  |   |                                  |  |  |  |  |
|  |  |   |                                  |  |  |  |  |
|  |  |   |                                  |  |  |  |  |
|  |  |   |                                  |  |  |  |  |
| Further  | documents are listed in the continuation of Box C.   | See patent family annex.  |                                  |  |  |  |  |
| "A" document   | pecial categories of cited documents:  defining the general state of the art which is not considered to be tlar relevance                | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |                                  |  |  |  |  |
| "E" earlier ap   | plication or patent published on or after the international filing date  | "X" document of particular relevance; the considered novel or cannot be consider when the document is taken alone   | red to involve an inventive step |  |  |  |  |
| "L" document<br>establish<br>specified)  | which may throw doubts on priority claim(s) or which is cited to<br>the publication date of another citation or other special reason (as | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination |                                  |  |  |  |  |
| "O" document referring to an oral disclosure, use, exhibition or other means   |  | being obvious to a person skilled in the  |                                  |  |  |  |  |
| "P" document published prior to the international filing date but later than the "&" document member of the same patent family priority date claimed       |  |   |                                  |  |  |  |  |
| Date of the actual completion of the international search  Date of mailing of the international search report  18 MAD 2002                                 |  |   |                                  |  |  |  |  |
| 16 January 2002 (16.01.2002)  Name and mailing address of the ISA/US  Authorized officer  Authorized officer   |  |   |                                  |  |  |  |  |
| Commissioner of Patents and Trademarks Box PCT  Bradley L. Sisson  Torrespond to the commissioner of Patents and Trademarks Bradley L. Sisson              |  |   |                                  |  |  |  |  |
|  | shington, D.C. 20231<br>p. (703)305-3230   | Telephone No. (703) 308-0196  |                                  |  |  |  |  |

Form PCT/ISA/210 (second sheet) (July 1998)



# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/23046

## BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

- a) the 2,783,486,160 species encompassed by SEQ ID NO:1 (claim 1);
- b) the 375 species encompassed by SEQ ID NO:2 (claim 6);
- c) the 160 species encompassed by SEQ ID NO:3 (claim 10);
- d) the 16 species encompassed by SEQ ID NO:4 (claim 15);
- e) the 1,209,158,496 species encompassed by SEQ ID NO:5 (claim 18);
- f) the 55,440 species encompassed by SEQ ID NO:6 (claim 23);
- g) the 136,080 species encompassed by SEQ ID NO:7 (claim 28); and
- f) the 57 species encompassed by claim 41.

Continuation of 1(ii).

Claims 1-5 and 32-40 relate to the first invention and will be searched to the extent that they read on the first disclosed peptide species: SEQ ID NO:8

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the species is directed to a peptide that has a different amino acid compound and as such constitute different invnetions. Accordingly, the species of polypeptides are not so linked by a special technical feature that they have unity of invention.

**Continuation of B. FIELDS SEARCHED Item 3:** 

EAST, STN Registry File Search terms: SEQ ID NO:8

#### NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty and of the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

#### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

# What parts of the international application may be amended?

The claims only.

The description and the drawings may only be amended during international preliminary examination under Chapter II.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are seceived by the international Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

# Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A sepiscoment short must be submitted for each short of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

## What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confounded with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.